

00/10/00
JC490
09/612055
07/07/00

Case Docket No.: SKLAR-21

Assistant Commissioner For Patents
Washington, D.C. 20231

JC490 U.S. PTO
09/612055
07/07/00

Transmitted herewith for filing is the patent application of:

Inventor: Joseph H. Sklar
For: LIGAMENT SHIM

Enclosed are:

- ☒ 19 sheets of drawings.
☐ An assignment of the invention to: _____
☒ A verified statement to establish small entity status.
☐ _____

The filing fee has been calculated as shown below:

For:	No. Filed	No. Extra	Rate	Small Entity	Rate	Large Entity
				Fee		Fee
Basic Fee				\$ 345.00		\$
Total Claims	2 - 20	0	x \$ 9.00	0.00	x \$ 18.00	
Ind. Claims	2 - 3	0	x \$ 39.00	0.00	x \$ 78.00	
Mult. Claims			+ \$ 130.00		+ \$ 260.00	
Total \$ 345.00						

☐ Please charge my Deposit Account No. 16-0221 to cover the filing fee and assignment recording fee. A duplicate copy of this sheet is enclosed.

☒ A check in the amount of \$345.00 to cover the filing fee (and assignment recording fee) is enclosed.

☒ The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 16-0221. A duplicate copy of this sheet is enclosed.

- ☒ Any additional filing fees required under 37 CFR 1.16.
☒ Any patent application processing fees under 37 CFR 1.17.

☒ The Commissioner is hereby authorized to charge payment of the following fees during the pendency of this application or credit any overpayment to Deposit Account No. 16-0221. A duplicate copy of this sheet is enclosed.

- ☒ Any patent application processing fees under 37 CFR 1.17.
☐ The issue fee set in 37 CFR 1.18 at or before mailing of the Notice of Allowance, pursuant to 37 CFR 1.311(b).
☒ Any filing fees under 37 CFR 1.16 for presentation of extra claims.

Respectfully submitted,

Marylandini 7/7/00
Pandiscio & Pandiscio
470 Totten Pond Road
Waltham, Massachusetts 02451-1914
Tel. (781) 290-0060

MB/SKLAR21.FEE

07/07/00
1c613 U.S. PTO

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Joseph H. Sklar
Title: LIGAMENT SHIM
Attorney's Docket No.: SKLAR-21

Assistant Commissioner For Patents
Washington, D.C. 20231

VERIFIED STATEMENT CLAIMING SMALL BUSINESS ENTITY
STATUS - INDEPENDENT INVENTOR

I, Joseph H. Sklar, a citizen of the United States of America residing at 210 Park Drive, Longmeadow, Massachusetts 01106, as the inventor named in the above-identified application, hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for the purposes of paying reduced fees under Title 35, United States Code, Sections 41(a) and (b), to the United States Patent and Trademark Office with regard to the invention described and claimed in the above-identified U.S. Patent Application; that I have not assigned, granted, conveyed or licensed, nor based upon information and belief am I under any obligation under contract or law to assign, grant, license or convey, any rights in said invention to any person who could not likewise be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization as defined in 37 CFR 1.9(d) and (e), respectively.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18, United States Code, Section 1001, and that such willful false statements may jeopardize the validity of the above-identified application, any patent issuing thereon, or any patent to which this verified statement is directed.

Date: 7/7/00

Joseph H. Sklar

MB/SKLAR21.VS

APPLICATION
FOR
UNITED STATES LETTERS PATENT

PATENT APPLICATION

SPECIFICATION

TO ALL WHOM IT MAY CONCERN:

Be it known that Joseph H. Sklar of 210 Park Drive,
Longmeadow, Massachusetts 01106 has invented certain
improvements in LIGAMENT SHIM of which the following
description is a specification.

MB/SKLAR21.CVR

Numerous procedures have been developed to restore the ACL through a graft ligament replacement. In general, these ACL 2 replacement procedures (Fig. 2) involve drilling a bone tunnel 8 through the tibia 4 and up into the femur 6. Then a graft ligament 10, consisting of a harvested or artificial ligament or tendon(s), is passed through the tibial tunnel 12, across the interior of the joint, and up into the femoral tunnel 14. Then a distal portion of the graft ligament is secured in the femoral tunnel 14 and a proximal portion of the graft ligament is secured in the tibial tunnel 12.

There are currently several different ways to secure a graft portion in a bone tunnel. One way is to use an interference screw 16 (Fig. 2) to aggressively wedge the graft ligament against the side wall of the bone tunnel. Another way is to suspend the graft ligament in the bone tunnel with a suture 18 (Fig. 3) or a cross-pin 20 (Fig. 4). Still another way is to pass the graft ligament completely through the bone tunnel and affix the ligament to the outside of the bone with a screw and washer arrangement 22 (Fig. 2) or a staple (not shown).

Depending on the fixation device and its manner of use, some fixation will occur at the portion of the bone tunnel nearest to the interior of the joint, and some fixation will occur intermediate the bone tunnel or adjacent to the portion of the bone tunnel farthest from the interior of the joint. For example, an interference screw 16 set into the femur 6 will typically be positioned substantially adjacent to the interior of the joint 26 (Fig. 5); however, an interference screw 16 set into the tibia 4 will frequently be positioned relatively far from the interior of the joint 26 (Fig. 6). On the other hand, suture 18 (Fig. 3) and cross-pin 20 (Fig. 4) suspensions will typically effect securing intermediate the length of the bone tunnel or at the far end of the bone tunnel, and screw and washer fixations 22 (Fig. 2) will typically effect securing relatively far from the interior of the joint 26.

It has been observed that whenever the graft ligament is secured remote from the interior of the joint 26 (i.e., in the middle of the bone tunnel or adjacent to an outer surface of the bone), the graft ligament 10 will be relatively unsupported at the point

where the ligament 10 passes from the bone tunnel into the interior of the joint. As a result, as the knee flexes back and forth through its natural range of motion (Fig. 7), the graft ligament moves about within the mouth 28 of the bone tunnel, rubbing against the walls of the bone tunnel. Over time, this can cause damage to the graft ligament and the wear down the mouth 28 of the bone tunnel, both to the serious detriment of the patient. It can also result in enlargement of the entire tunnel diameter, e.g., as show at 30. Less than a tight fit may result in incursion of synovial fluid into the tunnel, which is hypothesized to contribute to the tunnel-widening phenomenon.

The solution to this problem is to provide a shim 32 for insertion into the mouth 28 of the bone tunnel (Fig. 8). The shim 32 is formed and sized so as to take up additional space present at the mouth 28 of the bone tunnel and, at the same time, to urge the ligament against the opposing side walls of the bone tunnel. By taking up additional space at the mouth of the bone tunnel, the aforementioned windshield wiper effect can be effectively eliminated. In addition, the entrance

to the bone tunnel will be better sealed against migration of synovial fluid out of the joint and into the bone tunnel. This can be important, since incursion of synovial fluid into the bone tunnel is believed to be deleterious to the ligament reconstruction and to contribute to tunnel widening. At the same time, by urging the graft ligament 10 against the opposing side walls of the bone tunnel 8, osseo-integration between the graft ligament and the host bone will be enhanced. If desired, the shim 32 can be sized and positioned so as to force the ligament 10 against the opposing side walls of the bone tunnel 8 with substantial force so as to enhance attachment of the graft ligament 10 to the bone. However, it should also be appreciated that it is not necessary for the ligament shim 32 to force the ligament against the opposing side walls of the bone tunnel with any great force, since the primary purpose of the shim is simply to occupy excess bone tunnel space, not to compressively secure the ligament to the bone. In other words, the primary purpose of the ligament shim is to form a strategically-placed extension of the bone

tunnel wall, rather than to replace an interference screw.

The ligament shim can take the form of two basic embodiments; a peripheral shim 34 and a centerline shim 36.

The peripheral shim 34 is adapted to fit between the graft ligament 10 and a wall of the bone tunnel (Fig. 9). Thus, the shim effectively provides an extension of the bone wall which it lies against, so as to eliminate the windshield wiper effect discussed above. In one form of the invention, the shim 34 is intended to be held in place through a simple friction fit between the wall of the bone tunnel and the graft ligament. If desired, the shim can be tapered (Figs. 8 and 9) so as to give it a wedge-like configuration and/or the surfaces of the shim can be configured with ribs and/or roughening so as to increase friction with the adjacent anatomy. In another form of the invention, the shim can be suspended by a suture 38 which passes through a shim hole 39 (Fig. 10). Preferably, a shim has at least its outer surface in the shape of an arc (Fig. 11), so that it can conform to the round bone tunnel wall. In one embodiment, the

shim has both its inner and outer surfaces in the shape of an arc 42 (Fig. 11A), so that it can conform to both the round bone tunnel wall and the round graft ligament. If desired, more than one shim can be applied about the periphery of the mouth of the bone tunnel. Alternatively, a single shim can be constructed so that it covers a significant portion of the periphery of the bone tunnel wall.

In some circumstances, the graft ligament consists of single strand of tissue (Fig. 9). In other circumstances, the graft ligament consists of two or more strands 44 of tissue which extend parallel to one another so as to collectively form the graft ligament 10 (Fig. 12). For example, suture and cross-pin suspensions are typically created by looping a long hamstring graft 44 over a suture loop or cross-pin; in this case, there are two graft ligament strands extending parallel to one another in the bone tunnel. The centerline shim 36 is adapted to fit between two such graft ligament strands 44. The centerline shim 36 can be maintained in place through a simple friction fit between the two ligament strands 44 (Fig. 12). Again, the shim can be tapered along its

length so as to give it a wedge-like configuration, and/or the surfaces of the shim can be configured with ribs and/or roughening so as to increase friction with adjacent anatomy. Alternatively, the shim can be suspended by a suture 38 passing through a shim hole 39 (Fig. 13). Preferably, the centerline shim has its two opposing surfaces in the shape of an arc 46, so that the shim can conform to the two round graft ligament strands (Fig. 14). This construction will help keep the centerline shim 36 seated between the ligament strands 44. In some cases, more than two ligament strands 44 might be used in the ligament reconstruction. For example, four ligament strands might be used in the reconstruction. In this case, the shim might comprise four arced surfaces 48 (Fig. 15). Numerous implementations of the centerline shim 36 are contemplated (Fig. 16).

Both the peripheral shim and the centerline shim also provide a benefit beyond simply curing the aforementioned windshield wiper effect. More specifically, at the same time that the shims take up excess room within the bone tunnel, they also urge the graft ligament into engagement with the walls of the

bone tunnel. This urging facilitates osseo-integration between the graft ligament and the host bone, thereby improving surgical results.

In some cases, it may be necessary to redo, or "revise", an earlier ACL reconstruction. This frequently involves forming a new bone tunnel hole adjacent to the old bone tunnel hole. If the old bone tunnel hole 50 occupied a less than ideal position in the host bone 52, it is generally desirable to place the new bone tunnel hole 54 in a better position than the old bone tunnel hole. In some circumstances, the new bone tunnel hole will be placed so close to the old bone tunnel 50 hole that the two will actually overlap (Fig. 17). In this case, there may be a danger of a graft ligament strand 10 "falling" out of the new bone tunnel hole and into the old bone tunnel hole, e.g., as show at 56. With the present invention, a peripheral shim 34 may be used (Fig. 18) so as to close off the new bone tunnel hole 54 from the old bone tunnel hole 50, so as to keep the graft ligament strand from falling into the old bone tunnel hole 50.

It should be appreciated that while the present invention has been discussed above in the context of an

SKLAR-21

What Is Claimed Is:

1. A ligament shim for insertion into a bone tunnel, the bone tunnel forming a mouth and having at least one ligament extending through the mouth, the at least one ligament and the mouth forming an interstitial space, said ligament shim comprising a body having at least two walls extending in a first direction and defining a cross-sectional area in a second direction, said cross-sectional area conforming to at least a portion of the interstitial space defined by the at least one ligament extending through the mouth, whereby when said shim is placed in said interstitial space between the mouth and the at least one ligament, said shim will hold the at least one ligament against a wall of the bone tunnel.

2. A method for securing at least one ligament to a bone within a bone tunnel, the bone tunnel having a transverse cross-sectional area greater than a transverse cross-sectional area of the ligament, said method comprising:

inserting said ligament shim into the bone tunnel
so as to occupy a portion of the transverse
cross-sectional area of said bone tunnel.

Abstract

A shim for placement in a bone tunnel during ligament reconstruction.

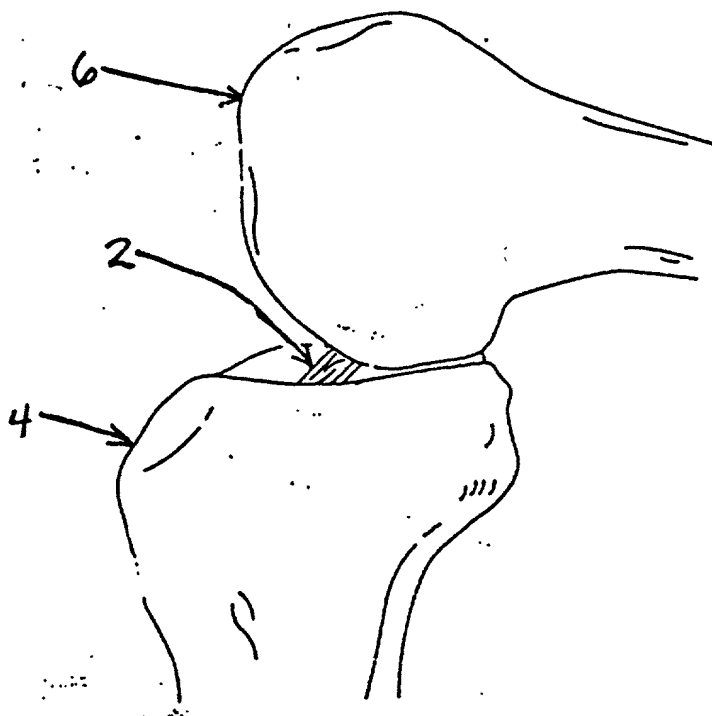


FIG. 1

09643035-0700

007020-9902T960

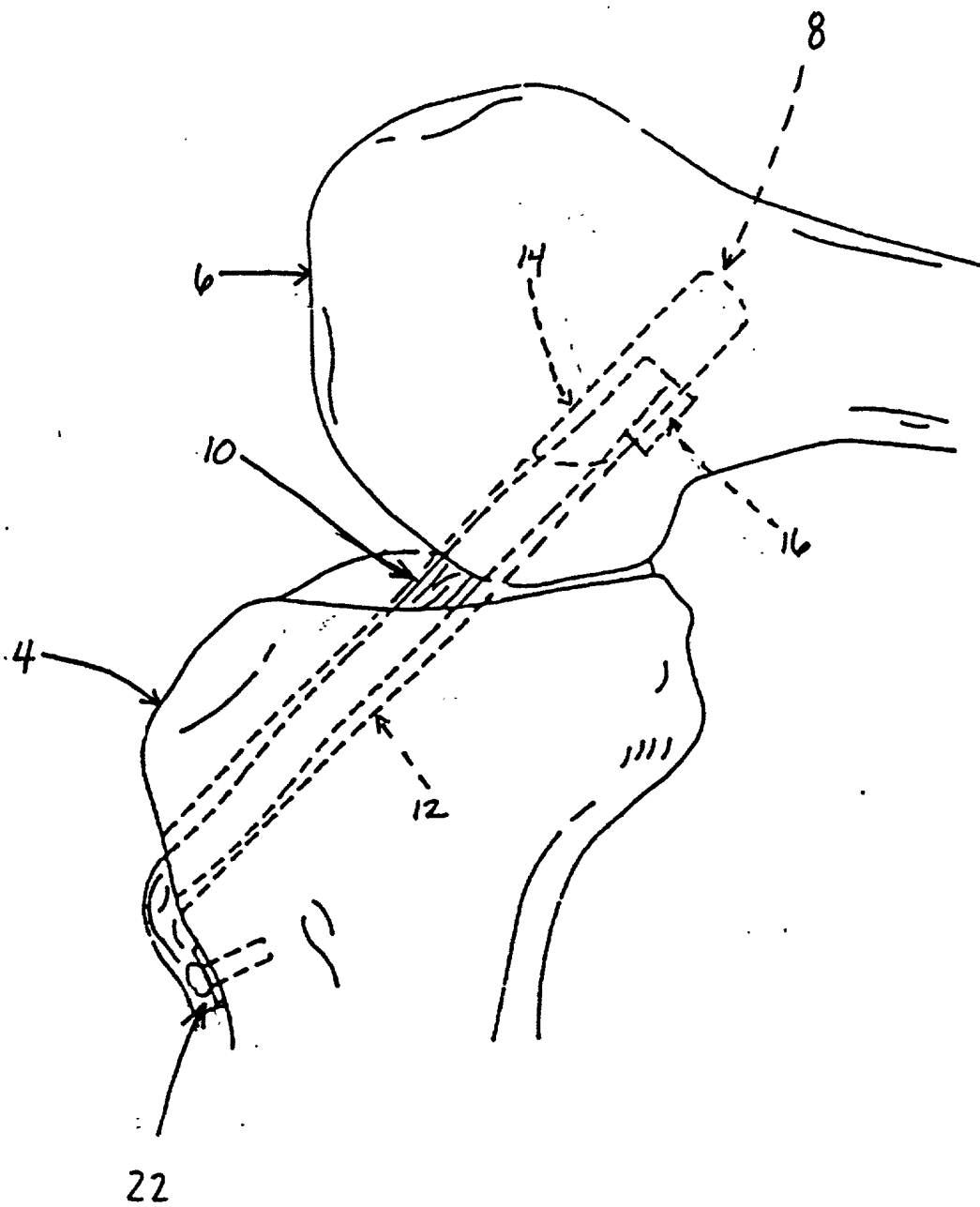


FIG. 2

This technical drawing illustrates a mechanical assembly, possibly a prosthetic joint component or a specialized fastener. The main body consists of two large, curved sections joined at a central point. A dashed line, labeled 14, runs diagonally across the center, representing an internal axis or a guide. At one end of this dashed line, there is a circular feature with a cross-hatch pattern, labeled 18. Another dashed line, labeled 12, extends from the bottom left towards the center. A solid line, labeled 10, points to the upper right section of the main body. A curved arrow, labeled 6, indicates a rotational movement around the upper part of the assembly. A small rectangular feature, labeled 4, is located on the lower left side. A dashed line, labeled 22, is shown near the bottom left corner. The overall design suggests a complex mechanical linkage or a specialized fastening mechanism.

FIG. 3

09542055-070708

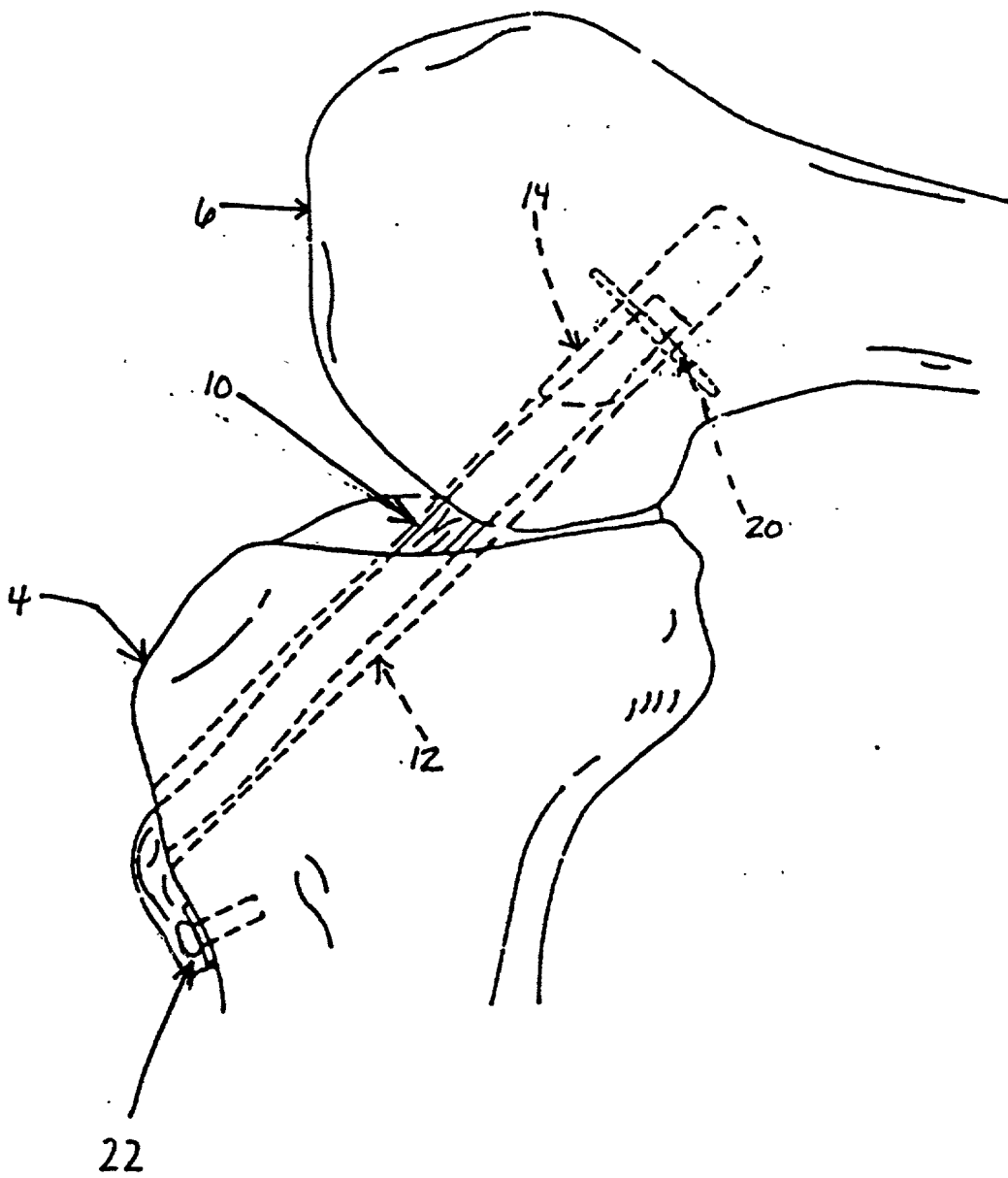
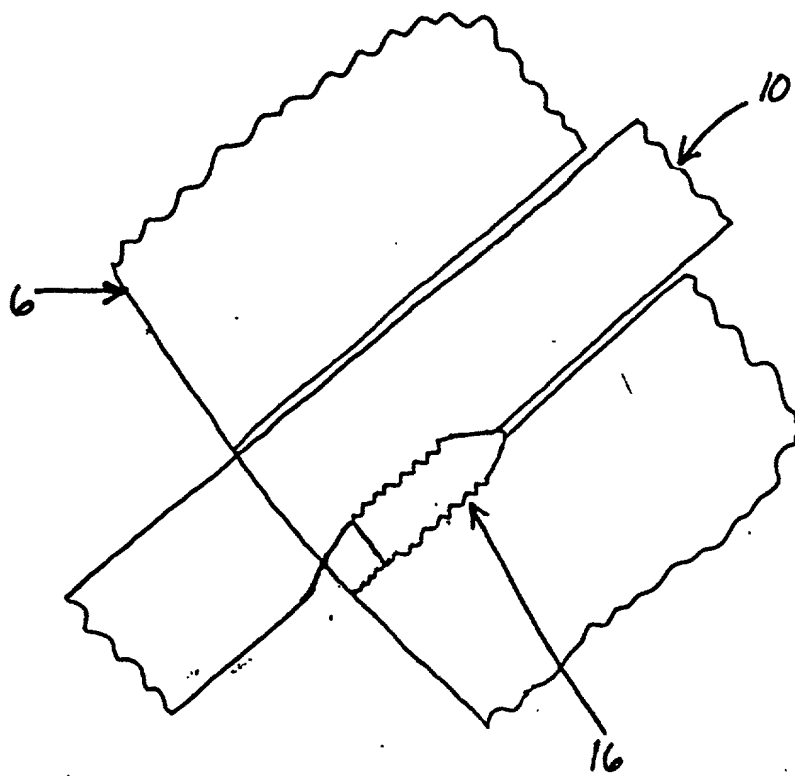


FIG. 4



26

FIG. 5

09642645.070700

1907 1908 1909 1910 1911 1912 1913 1914 1915 1916 1917 1918 1919 1920 1921 1922 1923 1924 1925 1926 1927 1928 1929 1930 1931 1932 1933 1934 1935 1936 1937 1938 1939 1940 1941 1942 1943 1944 1945 1946 1947 1948 1949 1950 1951 1952 1953 1954 1955 1956 1957 1958 1959 1960 1961 1962 1963 1964 1965 1966 1967 1968 1969 1970 1971 1972 1973 1974 1975 1976 1977 1978 1979 1980 1981 1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030 2031 2032 2033 2034 2035 2036 2037 2038 2039 2040 2041 2042 2043 2044 2045 2046 2047 2048 2049 2050 2051 2052 2053 2054 2055 2056 2057 2058 2059 2060 2061 2062 2063 2064 2065 2066 2067 2068 2069 2070 2071 2072 2073 2074 2075 2076 2077 2078 2079 2080 2081 2082 2083 2084 2085 2086 2087 2088 2089 2090 2091 2092 2093 2094 2095 2096 2097 2098 2099 2100 2101 2102 2103 2104 2105 2106 2107 2108 2109 2110 2111 2112 2113 2114 2115 2116 2117 2118 2119 2120 2121 2122 2123 2124 2125 2126 2127 2128 2129 2130 2131 2132 2133 2134 2135 2136 2137 2138 2139 2140 2141 2142 2143 2144 2145 2146 2147 2148 2149 2150 2151 2152 2153 2154 2155 2156 2157 2158 2159 2160 2161 2162 2163 2164 2165 2166 2167 2168 2169 2170 2171 2172 2173 2174 2175 2176 2177 2178 2179 2180 2181 2182 2183 2184 2185 2186 2187 2188 2189 2190 2191 2192 2193 2194 2195 2196 2197 2198 2199 2200 2201 2202 2203 2204 2205 2206 2207 2208 2209 2210 2211 2212 2213 2214 2215 2216 2217 2218 2219 2220 2221 2222 2223 2224 2225 2226 2227 2228 2229 2230 2231 2232 2233 2234 2235 2236 2237 2238 2239 2240 2241 2242 2243 2244 2245 2246 2247 2248 2249 2250 2251 2252 2253 2254 2255 2256 2257 2258 2259 2260 2261 2262 2263 2264 2265 2266 2267 2268 2269 2270 2271 2272 2273 2274 2275 2276 2277 2278 2279 2280 2281 2282 2283 2284 2285 2286 2287 2288 2289 2290 2291 2292 2293 2294 2295 2296 2297 2298 2299 2300 2301 2302 2303 2304 2305 2306 2307 2308 2309 2310 2311 2312 2313 2314 2315 2316 2317 2318 2319 2320 2321 2322 2323 2324 2325 2326 2327 2328 2329 2330 2331 2332 2333 2334 2335 2336 2337 2338 2339 2340 2341 2342 2343 2344 2345 2346 2347 2348 2349 2350 2351 2352 2353 2354 2355 2356 2357 2358 2359 2360 2361 2362 2363 2364 2365 2366 2367 2368 2369 2370 2371 2372 2373 2374 2375 2376 2377 2378 2379 2380 2381 2382 2383 2384 2385 2386 2387 2388 2389 2390 2391 2392 2393 2394 2395 2396 2397 2398 2399 2400 2401 2402 2403 2404 2405 2406 2407 2408 2409 2410 2411 2412 2413 2414 2415 2416 2417 2418 2419 2420 2421 2422 2423 2424 2425 2426 2427 2428 2429 2430 2431 2432 2433 2434 2435 2436 2437 2438 2439 2440 2441 2442 2443 2444 2445 2446 2447 2448 2449 2450 2451 2452 2453 2454 2455 2456 2457 2458 2459 2460 2461 2462 2463 2464 2465 2466 2467 2468 2469 2470 2471 2472 2473 2474 2475 2476 2477 2478 2479 2480 2481 2482 2483 2484 2485 2486 2487 2488 2489 2490 2491 2492 2493 2494 2495 2496 2497 2498 2499 2500 2501 2502 2503 2504 2505 2506 2507 2508 2509 2510 2511 2512 2513 2514 2515 2516 2517 2518 2519 2520 2521 2522 2523 2524 2525 2526 2527 2528 2529 2530 2531 2532 2533 2534 2535 2536 2537 2538 2539 2540 2541 2542 2543 2544 2545 2546 2547 2548 2549 2550 2551 2552 2553 2554 2555 2556 2557 2558 2559 2560 2561 2562 2563 2564 2565 2566 2567 2568 2569 2570 2571 2572 2573 2574 2575 2576 2577 2578 2579 2580 2581 2582 2583 2584 2585 2586 2587 2588 2589 2590 2591 2592 2593 2594 2595 2596 2597 2598 2599 2600 2601 2602 2603 2604 2605 2606 2607 2608 2609 2610 2611 2612 2613 2614 2615 2616 2617 2618 2619 2620 2621 2622 2623 2624 2625 2626 2627 2628 2629 2630 2631 2632 2633 2634 2635 2636 2637 2638 2639 2640 2641 2642 2643 2644 2645 2646 2647 2648 2649 2650 2651 2652 2653 2654 2655 2656 2657 2658 2659 2660 2661 2662 2663 2664 2665 2666 2667 2668 2669 2670 2671 2672 2673 2674 2675 2676 2677 2678 2679 2680 2681 2682 2683 2684 2685 2686 2687 2688 2689 2690 2691 2692 2693 2694 2695 2696 2697 2698 2699 2700 2701 2702 2703 2704 2705 2706 2707 2708 2709 2710 2711 2712 2713 2714 2715 2716 2717 2718 2719 2720 2721 2722 2723 2724 2

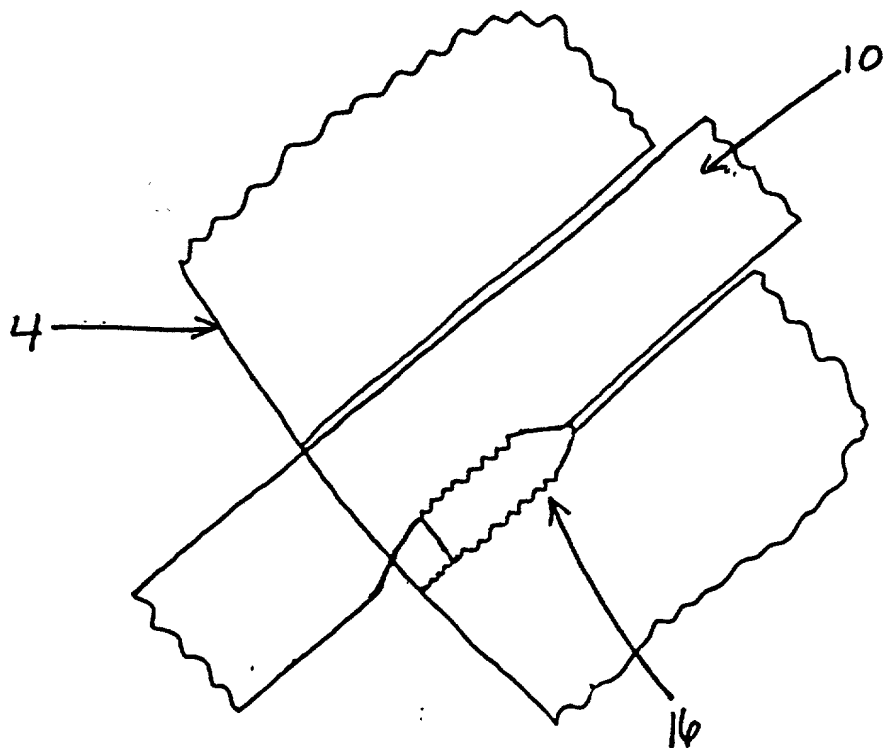
36

FIG. 6

004255-07000

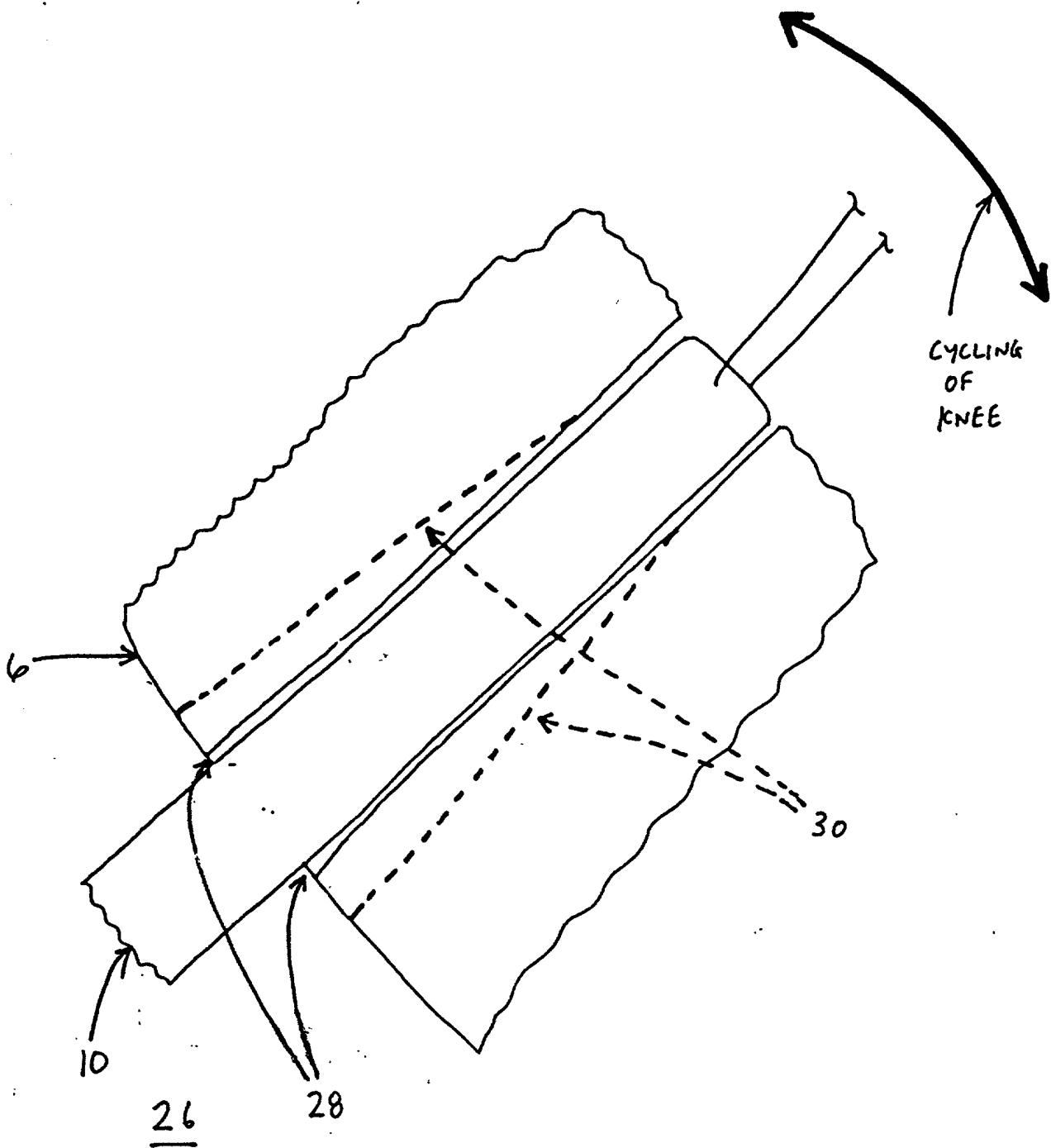


FIG. 7

00612055-070700

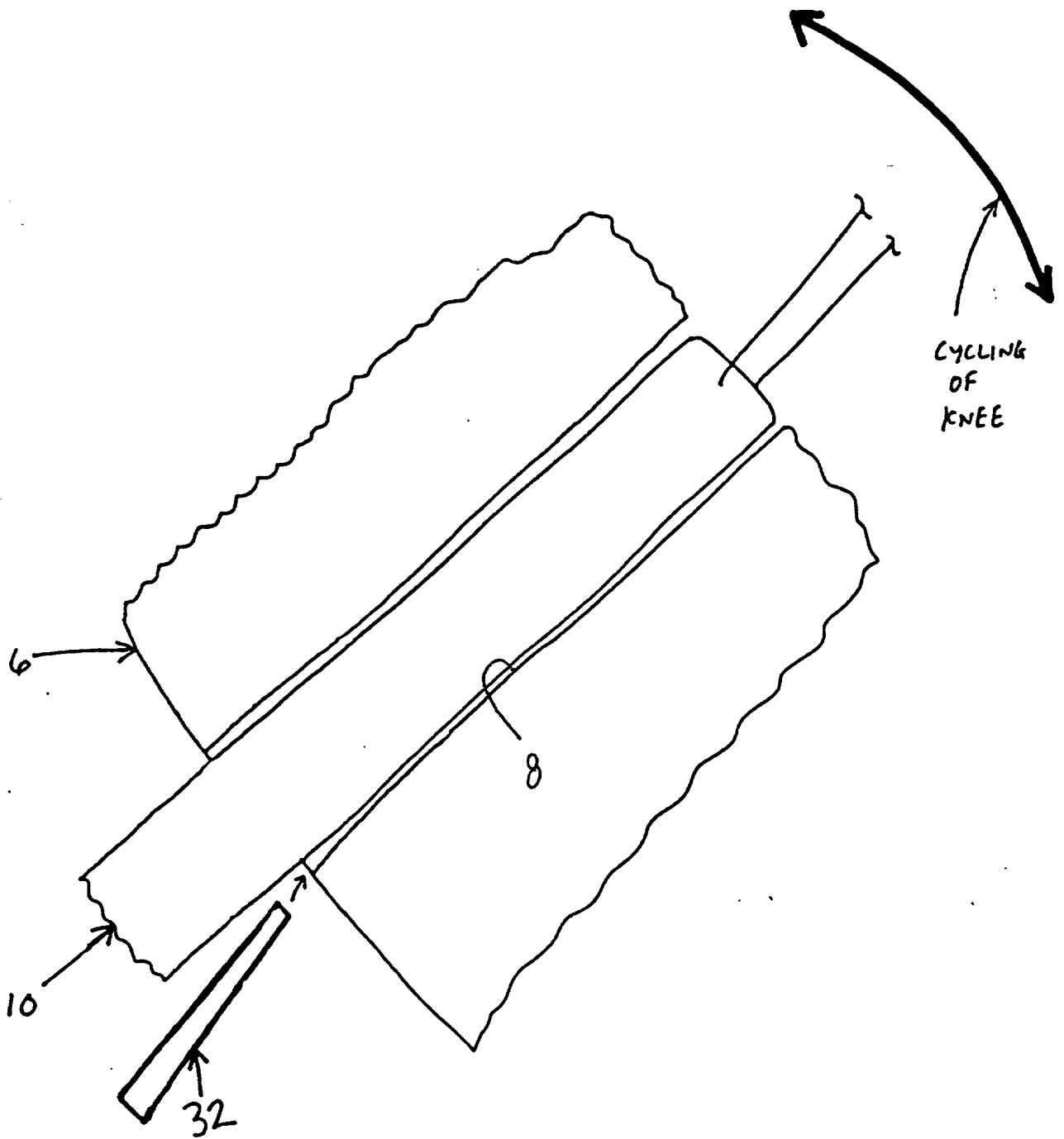


FIG. 8

004205-070700

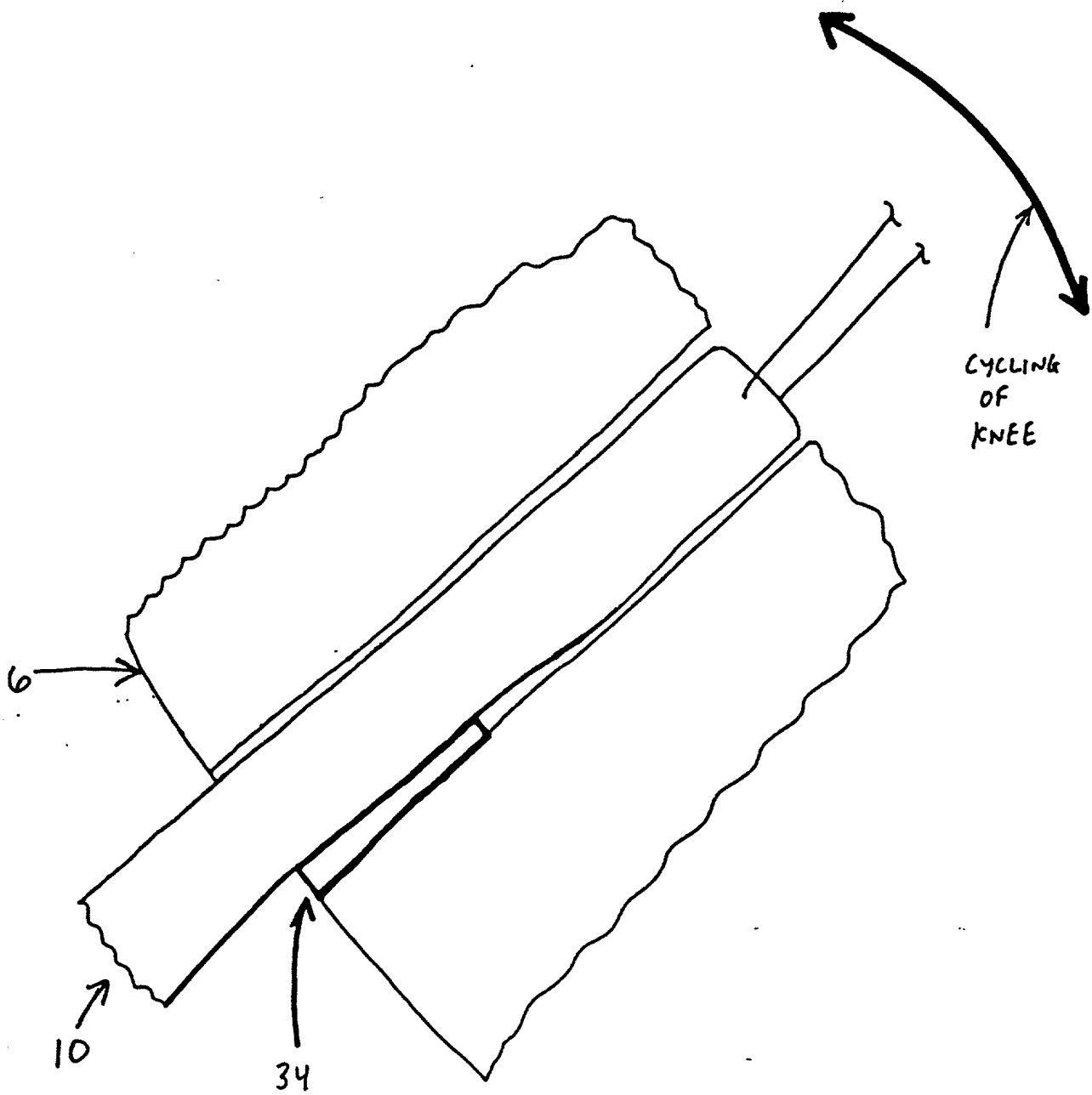


FIG. 9

4

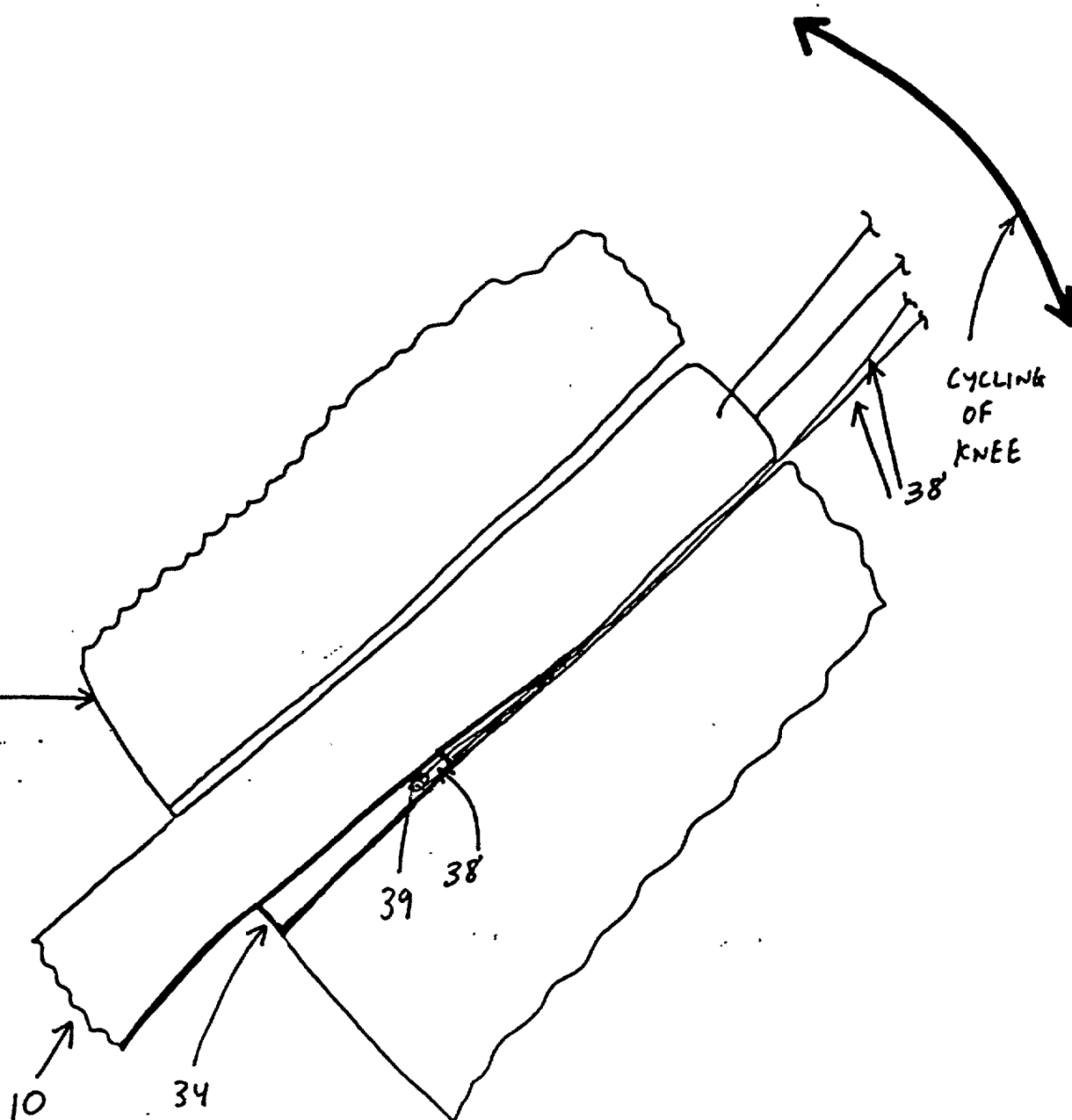


FIG. 10

09642616-070703

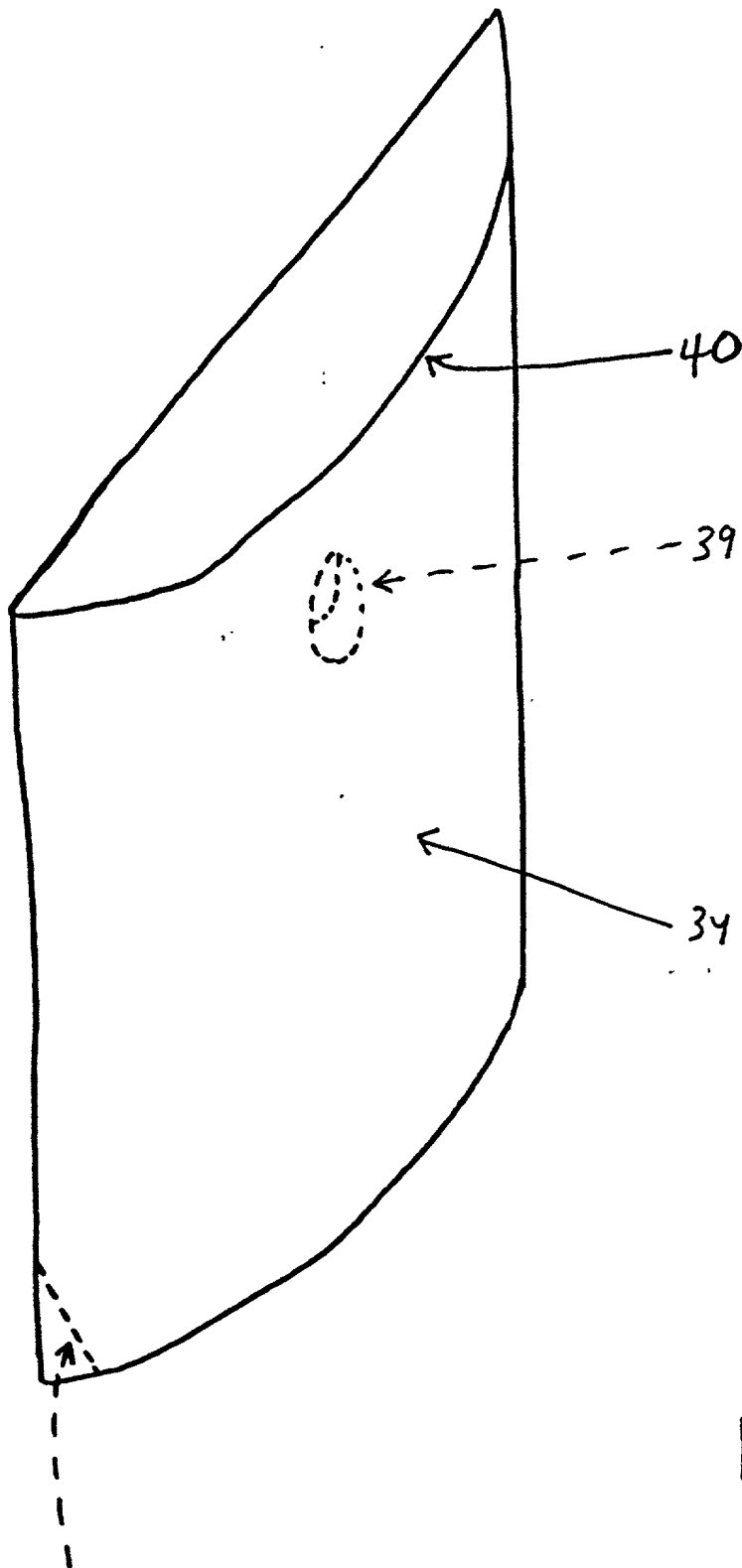


FIG. 11

OPTIONAL: ROUND SURFACES
NEAR MOUTH OF BONE TUNNEL,
TO PROVIDE GENTLE BEARING SURFACES
FOR LIGAMENT

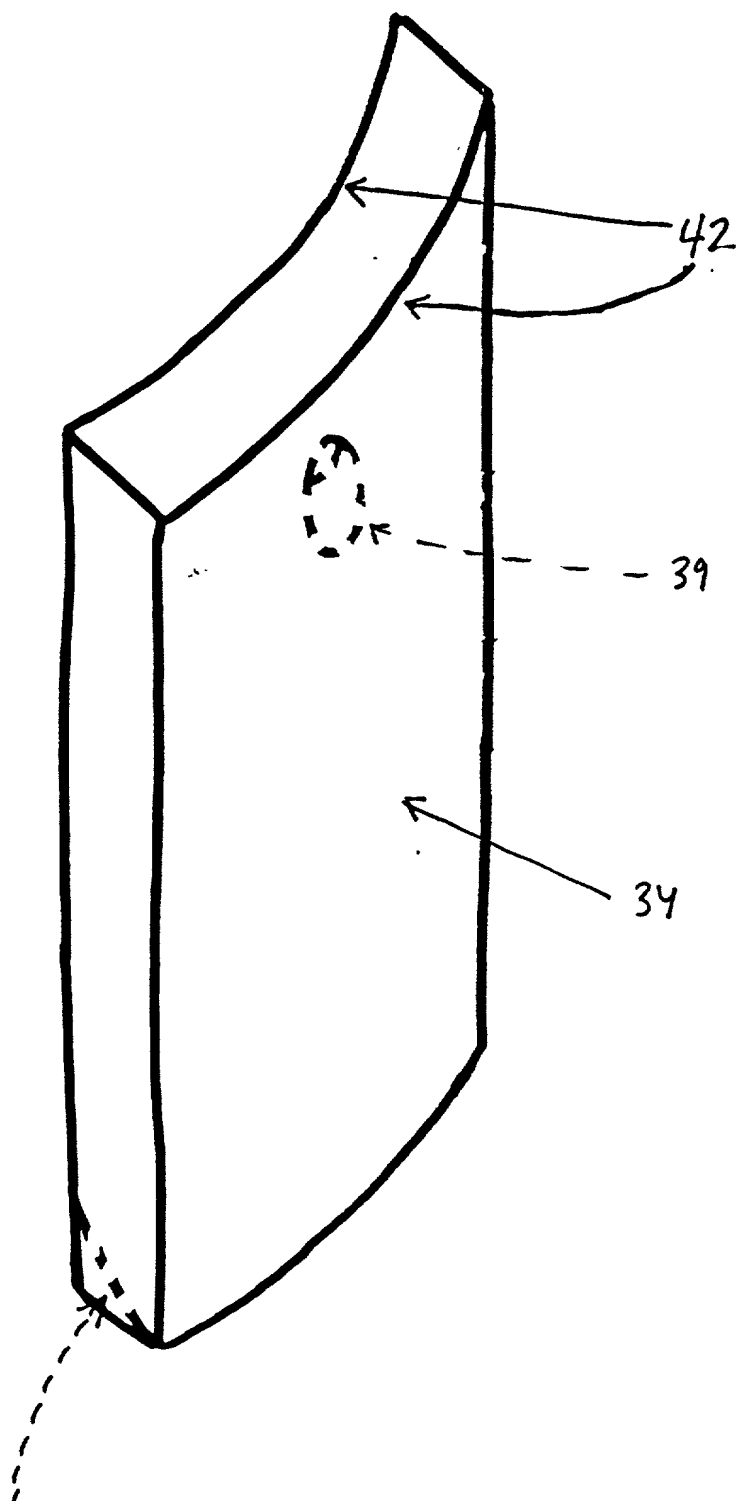


FIG. 11A

OPTIONAL: ROUND SURFACES NEAR
MOUTH OF BONE TUNNEL, TO PROVIDE
GENTLE BEARING SURFACES FOR
LIGAMENT

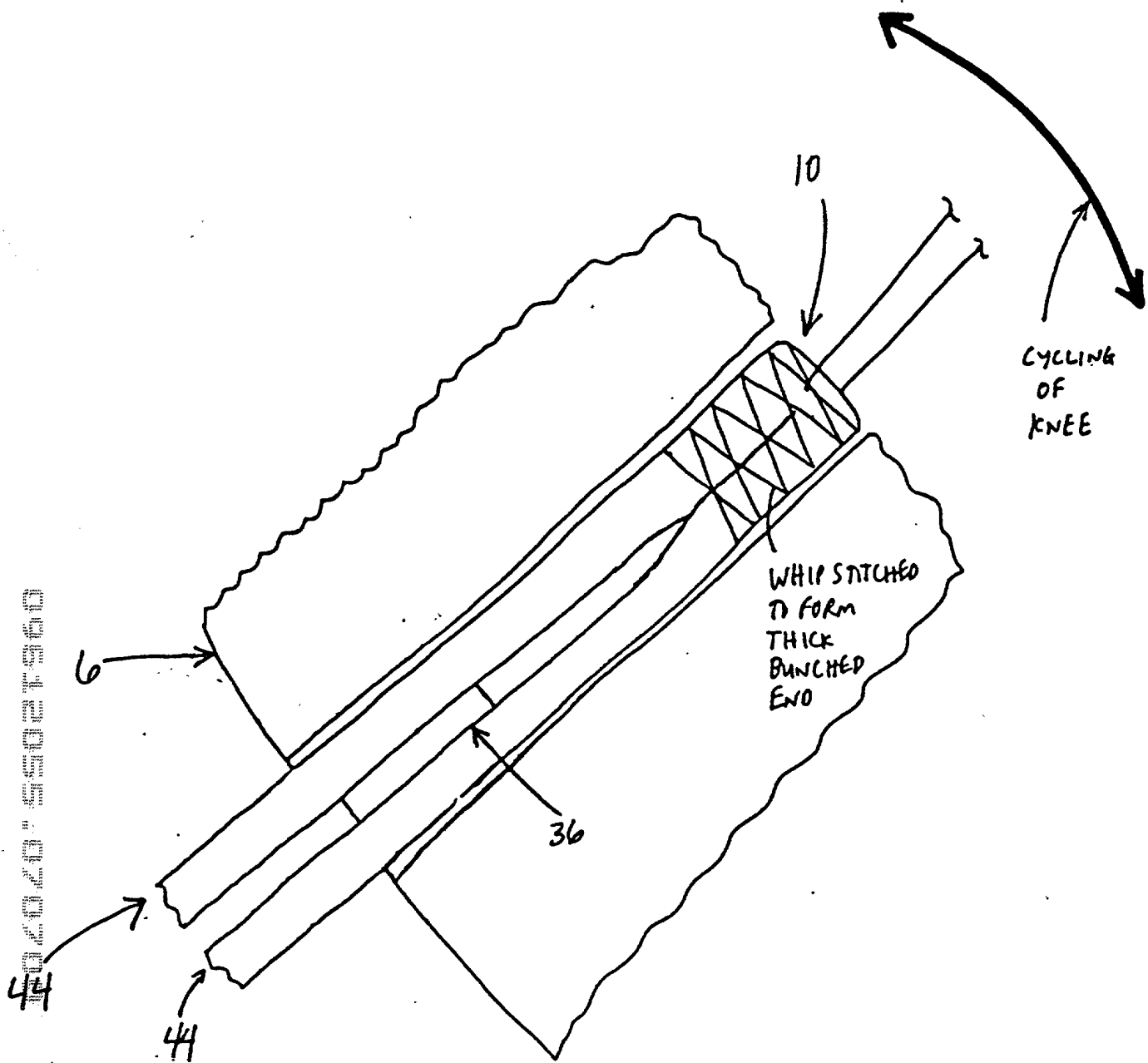


FIG. 12

002029592960

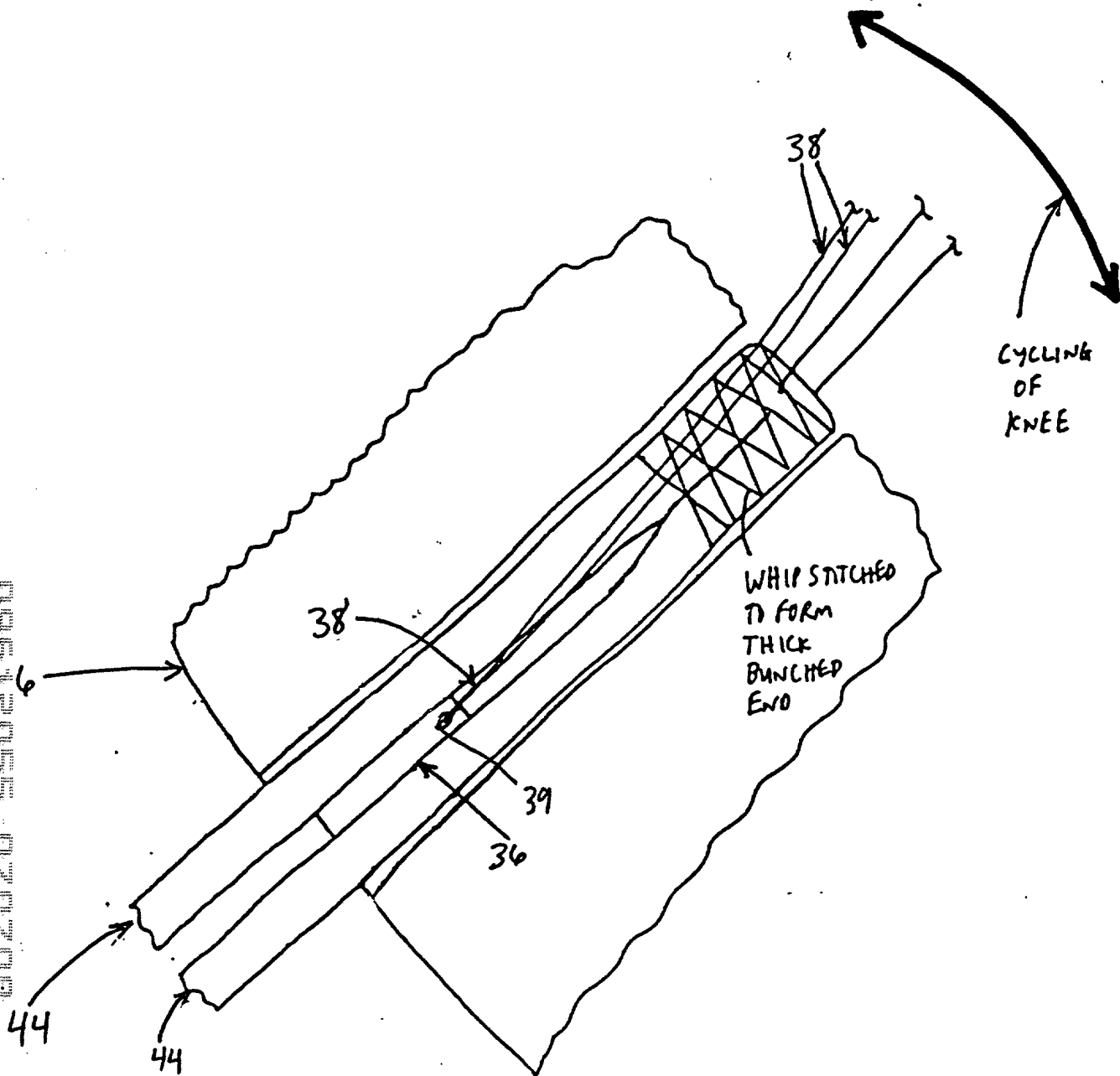


FIG. 13

OPTIONAL:
CAN BE
OUTWARDLY
ARLED TO
CONFORM
TO BONE
HOLE

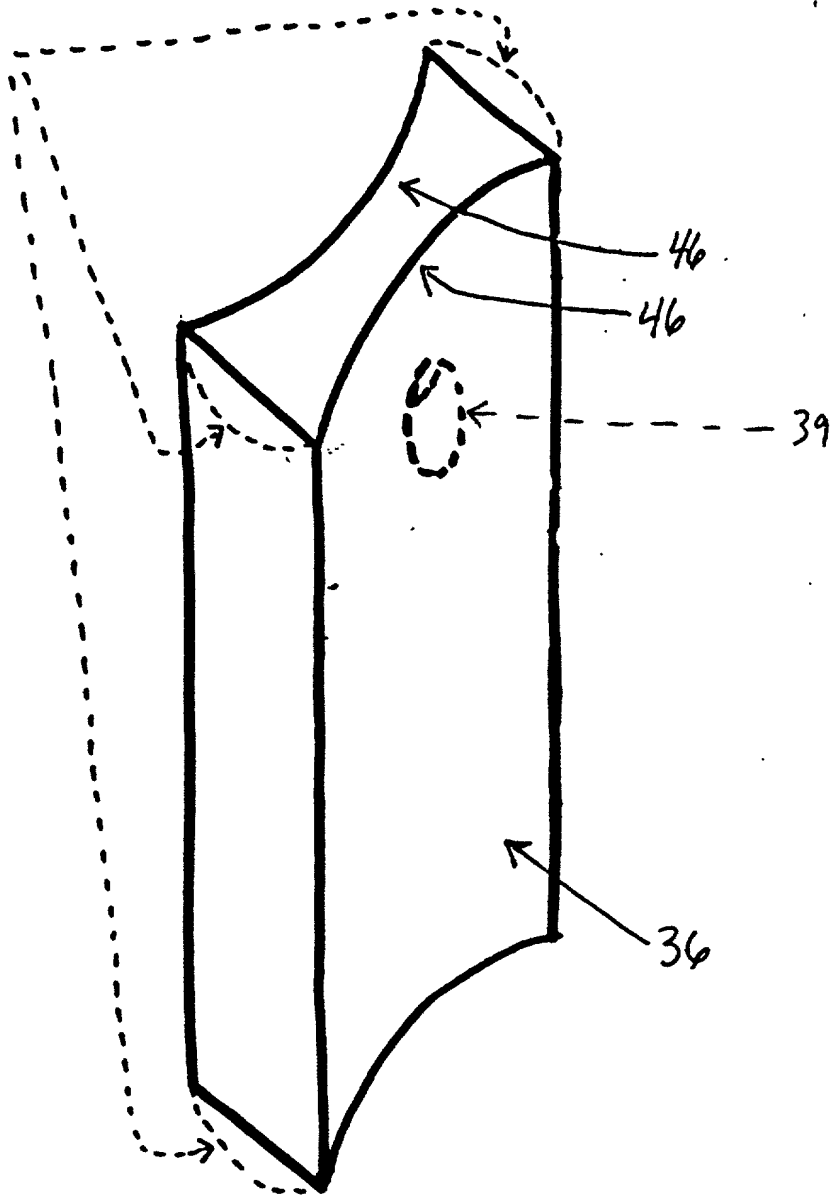


FIG. 14

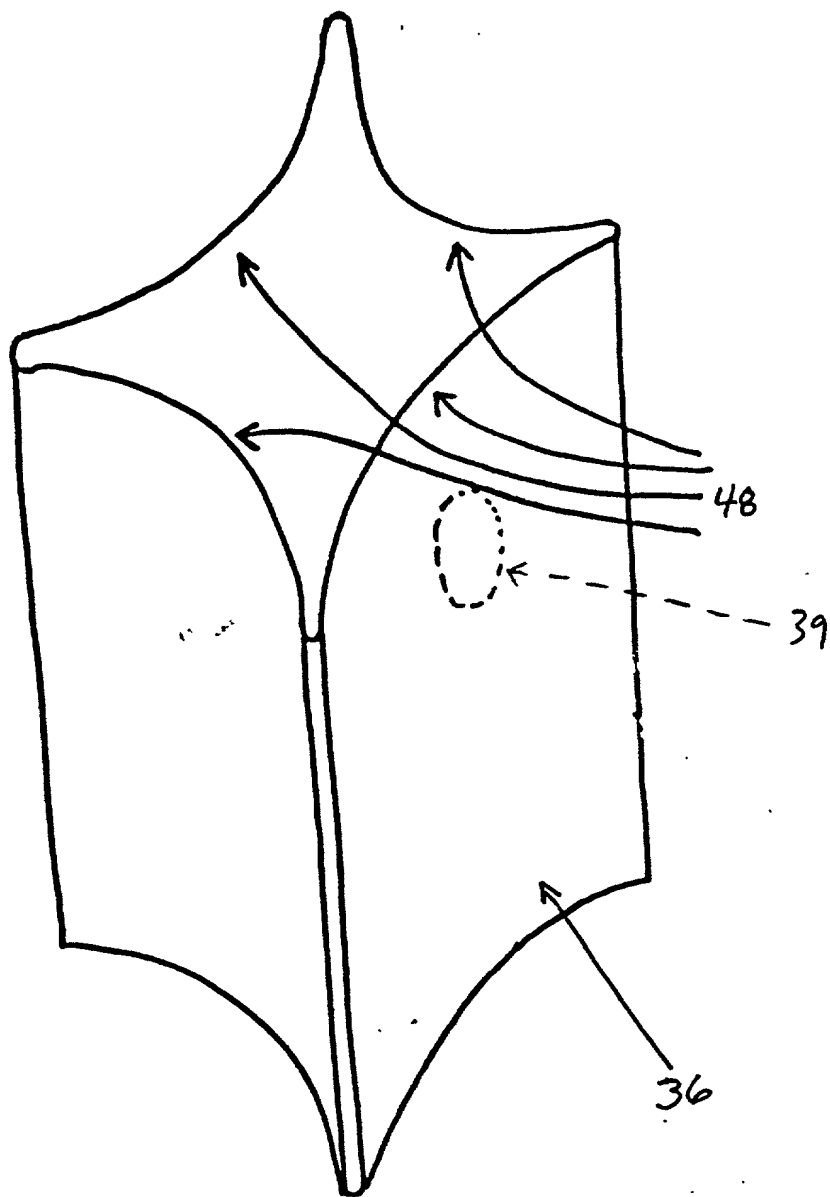


FIG. 15

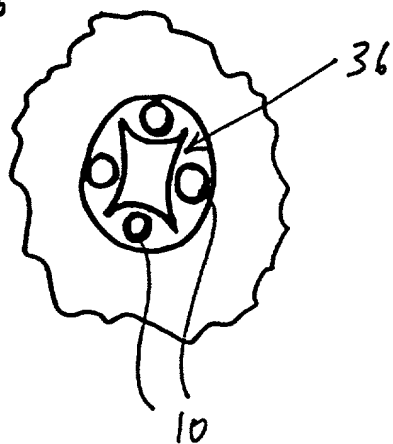
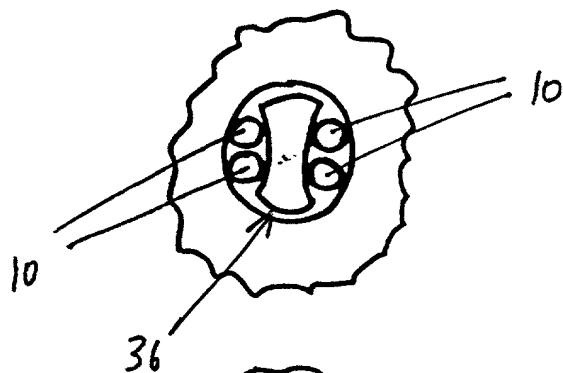
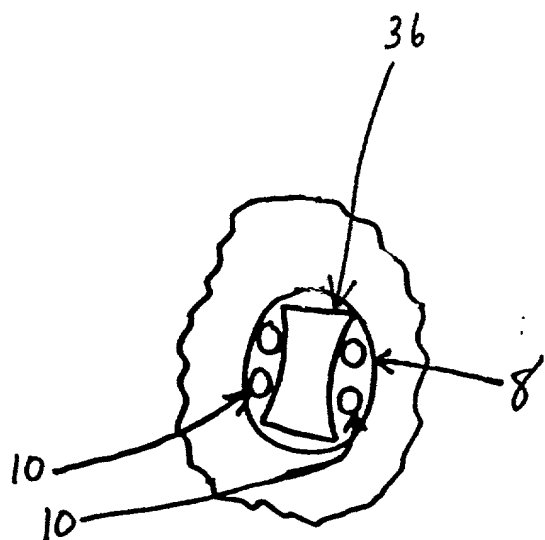


FIG. 16

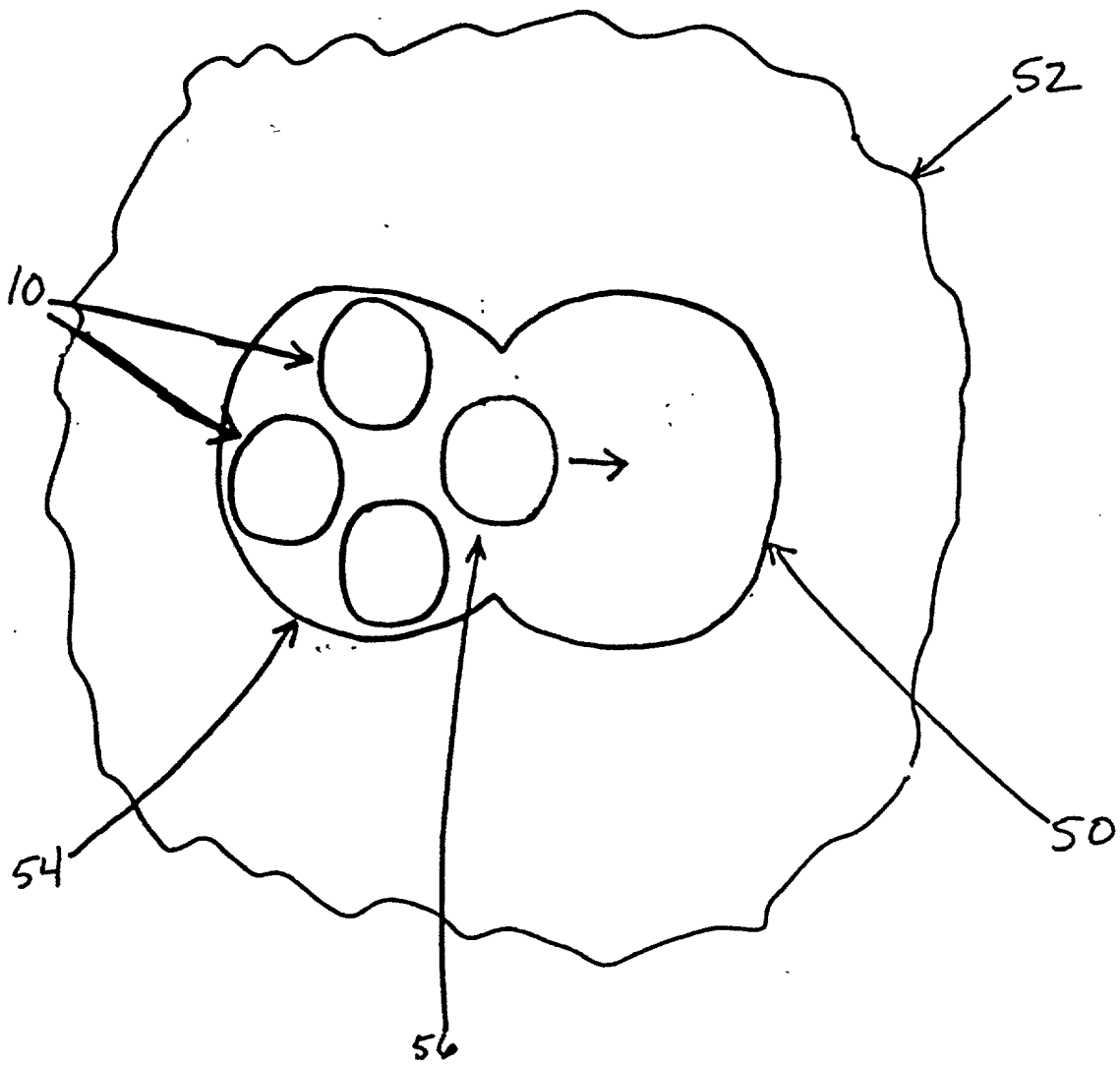


FIG. 17

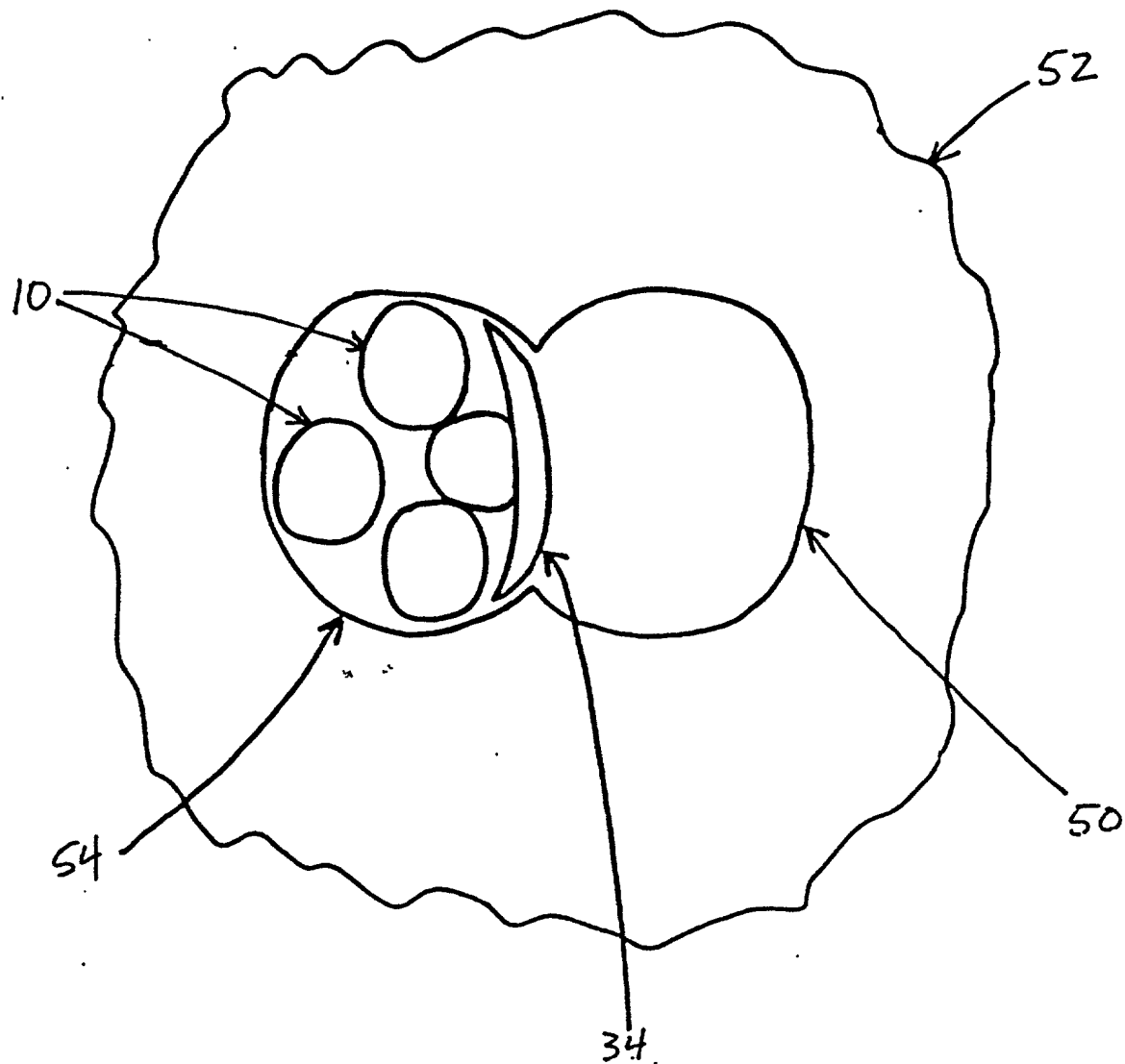


FIG. 18

DECLARATION AND POWER OF ATTORNEY

As a below-named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled "LIGAMENT SHIM", the specification of which is attached hereto and is identified by Attorney's Docket No. SKLAR-21.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

I hereby claim priority benefits under Title 35, United States Code, Section 119(e), of U.S. Provisional Patent Application Serial No. 60/143,241, filed 07/09/99 for LIGAMENT SHIM.

SKLAR-21

002020-4982960

I hereby appoint Pandiscio & Pandiscio, a firm composed of Nicholas A. Pandiscio, Registration No. 17293, Mark J. Pandiscio, Registration No. 30883, Scott R. Foster, Registration No. 20570, and James A. Sheridan, Registration No. 43,114 or any of them, of 470 Totten Pond Road, Waltham, Massachusetts 02451-1914, (Telephone No. 781-290-0060), my attorneys with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent Office connected therewith.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Inventor's signature:

Inventor's full name:

Date:

Residence:

Post office address:

Citizenship:

MR\SKLAR21.AP2



Joseph H. Sklar

7/7/00

210 Park Drive

Longmeadow, Massachusetts 01106

same

United States of America

SKLAR-21